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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,631	09/06/2000	Marilynn E. Etzler	23070-079820US	1727
20350	7590	04/21/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			BAUM, STUART F	
TWO EMBARCADERO CENTER			ART UNIT	PAPER NUMBER
EIGHTH FLOOR			1638	
SAN FRANCISCO, CA 94111-3834			DATE MAILED: 04/21/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/657,631	ETZLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 December 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,5,9,11,13 and 14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,5,9,11,13 and 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***RCE Acknowledgment***

1. The request filed on December 17, 2003 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/657,631 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1, 4-5, 9, 11, and 13-14 are pending and are examined in the present office action.

### ***Specification***

3. The specification, first paragraph, is objected to for not specifying that U.S. patent application 08/129,112 filed August 4, 1998, is now U.S. Patent 6,465,716.

### ***Claim Objection***

4. Claim 4 is objected to for reciting SEQ ID NO:5 instead of SEQ ID NO:8, as is stated in the previous version of the claims dated 2/26/2002 because Applicant cannot file a RCE to obtain examination of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions). See 35 U.S.C. 132(b). The claim will be examined as reading on SEQ ID NO:8.

### ***New Matter***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-5, 9, 11, and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to “selecting plants that have increased mycorrhizal infection”. The before mentioned claimed inventions do not have support in the presently filed application and are considered new matter.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5, 9, 11, and 13-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 7-8 of U.S. Patent No. 6,465,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4, and 7-8 of U.S. Patent No. 6,465,716 are

drawn to a transgenic plant with enhanced rhizobial binding to roots of said plant and method of enhancing rhizobial binding to roots comprising transforming said plant with a nucleic acid sequence that hybridizes under conditions that include at least one wash in 0.2 SSC at 60<sup>0</sup> C for 20 minutes and that encodes an NBP46 polypeptide that enhances rhizobial binding to roots of the plant, wherein said plant is not a legume and wherein the nucleic acid is introduced via a sexual cross.

Claims 1, 4-5, 9, 11, and 13-14 of the instant application are obvious over claims 1-4, and 7-8 of U.S. Patent No. 6,465,716 because the instant claims are drawn to a method of increasing mycorrhizal infection in a plant comprising transforming said plant with a nucleic acid sequence that encodes an LNP polypeptide at least about 70% identical to SEQ ID NO:10, wherein said nucleic acid sequence is operably linked to a promoter, wherein said promoter is from an LNP gene, wherein the nucleic acid is introduced into the plant via a sexual cross, wherein the method further comprises infecting said plant with a mycorrhizal fungus. It would have been obvious to one of skill in the art to modify the method steps from the '716 patent to encompass nucleic acid sequences that encode a LNP protein exhibiting at least about 70% identity with SEQ ID NO:10 or wherein the nucleic acid sequence is SEQ ID NO:8, given the recognition by those of ordinary skill in the art of the value of producing plants that are infected by mycorrhizae. Applicants have specified that LNP was formerly known as NBP46 (page 2, line 10).

***Written Description***

7. Claims 1, 5, 9, 11, 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of increasing mycorrhizal infection in a plant comprising introducing into the plant a nucleic acid that encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10.

Applicants have disclosed SEQ ID NO:1, 3, and 8 from *Dolichos biflorus*, *Medicago sativa* and *Lotus japonica*, respectively, encoding a LNP protein of SEQ ID NO:2, 4, and 10, respectively. Applicants have further disclosed characteristic features and functions of LNPs including carbohydrate binding activity, and four conserved sequence motifs characteristic of apyrase enzymes, and that LNPs are Nod factor binding proteins, and Applicants have disclosed degenerate primers to conserved sequences of *dochilos biflorus* LNP (page 6, 2<sup>nd</sup> paragraph of the Remarks submitted December 17, 2003).

Applicants' claims do not specify that the claimed sequences encompassing nucleic acid sequences encoding a polypeptide at least about 70% identical to SEQ ID NO:10 also encodes a polypeptide with the function of a Nod factor binding protein. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of

an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. In the instant application, Applicants have omitted the functional language. The court goes on to say, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants claims read on all sequences encoding any polypeptide that exhibits at least about 70% identity to SEQ ID NO:10, but Applicants fail to describe a representative number of polynucleotide sequences encoding said protein. Applicants only describe nucleic acid sequences encoding the three LNP polypeptides. Furthermore, Applicants fail to describe structural features common to the multitude of members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Amending the claims to recite that the claimed nucleic acids have the function of a Nod factor binding protein, will obviate the rejection.

#### *Scope of Enablement*

8. Claims 1, 5, 9, 11, 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing mycorrhizal infection in a plant comprising transforming a plant with a nucleic acid operably linked to a heterologous LNP

polynucleotide wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10 and functions as a Nod factor binding protein (see Applicants' remarks, page 6, 2<sup>nd</sup> paragraph, and 1.132 Declaration of Biao Wu Ph.D, filed 12/17/2003), does not reasonably provide enablement for claims drawn to a method of increasing mycorrhizal infection in a plant comprising transforming a plant with a nucleic acid operably linked to a heterologous LNP polynucleotide wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of increasing mycorrhizal infection in a plant comprising introducing into the plant a nucleic acid that encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10, wherein the nucleic acid is operably linked to a promoter in sense orientation and comprising infecting said plant with a mycorrhizal fungus.

Applicants have disclosed SEQ ID NO:1, 3, and 8 from *Dolichos biflorus*, *Medicago sativa* and *Lotus japonica*, respectively, encoding a LNP protein of SEQ ID NO:2, 4, and 10, respectively. Applicants have further disclosed characteristic features and functions of LNPs including carbohydrate binding activity, and four conserved sequence motifs characteristic of apyrase enzymes, and that LNPs are Nod factor binding proteins, and Applicants have disclosed degenerate primers to conserved sequences of *dochilos biflorus* LNP (page 6, 2<sup>nd</sup> paragraph of the Remarks submitted December 17, 2003). Applicants have also submitted a 1.132 Declaration of Biao Wu Ph.D. disclosing transforming *Arabidopsis* plants with plasmids that express the *Dolichos biflorus* LNP gene of SEQ ID NO:1 encoding the *Dolichos biflorus* LNP polypeptide of SEQ ID NO:2. *Arabidopsis* plants expressing the *Dolichos biflorus* LNP polypeptide of SEQ ID NO:2 exhibited external hyphae attached to the root surface while plants not transformed or plants transformed with an empty cassette did not have hyphae attached to the root surface.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode polypeptides at least about 70% identical to SEQ ID NO:10 will encode a protein with the same activity as a protein encoded by SEQ ID NO:10. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the

PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2<sup>nd</sup> paragraph).

Not all nucleic acid sequences encoding a polypeptide exhibiting at least about 70% identity to SEQ ID NO:10 encode a nod factor binding protein. Thomas et al teach (from WO 200052144, 9/8/2000 as referenced in the sequence search results of DNA's encoding SEQ ID NO:10, Result 8, included herein) a nucleic acid sequence encoding an Ecto-phosphatase from Pisum sativum. Thomas et al's nucleic acid sequence is used to increase the sensitivity of cells to chemotherapeutic and antibiotic agents.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed have increased mycorrhizal infection and function as a Nod binding factor, said nucleic acid sequences encode a polypeptide exhibiting at least about 70% identity with SEQ ID NO:10.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

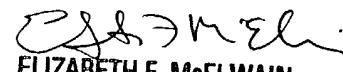
9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
April 2, 2004

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
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